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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,293	10/25/2000	Jeanne Bernstein	2786-0140P	9369
7590 10/20/2003 Birch Stewart Kolasch & Birch LLP PO BOX 747 Falls Church, VA 22040-0747			EXAMINER KETTER, JAMES S	
			ART UNIT 1636	PAPER NUMBER 16
DATE MAILED: 10/20/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER
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16

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

--See attached--

Office Action Summary

Application No.

09/695,293

Applicant(s)

BERNSTEIN ET AL.

Examiner

James S. Ketter

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-3,6-11 and 14-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 4,5,12 and 13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-3, 6-11 and 14-34 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 5, 12 and 13 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility, for reasons of record set forth in Paper No. 14, mailed 28 January 2003.

Claims 4, 5, 12 and 13 also stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record set forth in Paper No. 14, mailed 28 January 2003.

At the paragraph bridging pages 8 and 9 of the amendment filed 28 July 2003, Applicants argue that a prima facie case of lack of utility has not been made, alleging that a utility was asserted but that "the Examiner refuses to accept it." Further, they argue that the rejection is based on the personal opinion of the Examiner and not on art recognized scientific principles. However, the mere assertion of a utility is not sufficient where that utility is neither credible nor well-established. Contrary to Applicants' arguments, a scientifically reasoned basis for the rejection was set forth, with respect to the asserted utility of therapy. It is noted that Applicants

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have not commented upon the actual rationale of the rejection. With respect to the other asserted utility, i.e., detection, Applicants have not shown that any sort of detection methods employing the gene in question were known in the art, and have not shown where the specification sets forth any specificity in the employment of the claimed invention in any sort of detection method.

Applicant's arguments filed 28 July 2003 have been fully considered but they are not persuasive.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 5, 12 and 13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Arriza et al. (U), for reasons of record set forth in Paper No. 14, mailed 28 January 2003.

At page 6 of the amendment, Applicants argue that the reference teaches only the original sequence, not any splice variants, and that the sequence taught by the reference is therefore excluded from the claims. However, as will be discussed below, the term “original sequence” remains unclear, and as such, the claims must still be read broadly. Thus, it is not clear whether the sequence as set forth in the reference must be regarded as “original” or if it might be viewed as being a splice variant itself, with some other sequence being the “original” one.

Applicant's arguments filed 28 July 2003 have been fully considered but they are not persuasive.

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Claims 4, 5, 12 and 13 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record set forth in Paper No. 14, i.e., that the phrase “where the amino acid sequence differs from the original amino acid sequence, coded by the original nucleic acid sequence from which the variant has been varied” is unclear.

At page 7 of the amendment, Applicants argue that page 9, lines 1 and 2 of the specification that the term is defined as “the...sequence from which the variant of the invention have [sic] been varied as a result of alternative splicing.” But this merely begs the question. Any given form (variant) may be viewed as a variant of any other form (variant), due to alternative splicing. For example, if a factory manufactures blue paint and red paint, which color is the original and which is the variant? Applicants further point to page 21, in the table, to the MCR_HUMAN sequence, noting that the description of this sequence makes reference to the original sequence. However, this is merely a reference to the sequence, and not a definition of the sequence, as it does not teach the complete sequence information connected to the term “original”. As such, the term “original sequence” remains incompletely defined, and thus the metes and bounds of the claims remain undefined.

Applicant's arguments filed 28 July 2003 have been fully considered but they are not persuasive.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.


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Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
October 16, 2003



JAMES KETTER
PRIMARY EXAMINER